

REMARKS

The above-identified Application has been carefully reviewed with the Office Action of September 19, 2010, the Examiner's comments, and the art references cited therein in mind. In response thereto, Applicants submit the following arguments in support of patentability. Favorable reconsideration is hereby respectfully requested.

In response to this Office Action, Applicants submit the following arguments in support of patentability. Favorable reconsideration is hereby respectfully requested.

Claims 25-28 have been rejected under 35 U.S.C. 103 (a) as being unpatentable over *Gau et al.* (US 5,084,061).

The Office Action now holds that it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize dimensional tolerance as claimed since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

It is well established at law that, for a proper rejection of a claim under 35 U.S.C. §103 as being obvious based upon a single reference, the reference must disclose, teach, or suggest, either implicitly or explicitly, all elements/features/steps of the claim at issue. See, e.g., *In Re Dow Chemical*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988), and *In re Keller*, 208 U.S.P.Q.2d 871, 881 (C.C.P.A. 1981). Moreover, "[t]he mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." *In re Fritch*, 972 F.2d 1260, 1266, 23 U.S.P.Q.2d 1780 (Fed Cir. 1992) (emphasis added).

The Applicants respectfully disagree with the position taken by the Office because the one of ordinary skill in the art, at the time the invention was made, would not have obtained the same result of the invention in view of *Gau et al.*

Gau et al. teaches (Col. 4, lines 6 to 9): "... an inflatable elastomeric shell 22, which is preferably made from silicone rubber cast on a mandrel (not shown) to have a final thickness of approximately 0.006 to 0.025 inches. "

As described in the description of the invention, a method like this does not allow a good control of the dimensional tolerance of the elastomeric shell (Page 26, lines 16 to 25):

"Furthermore, the dipping method generally does not enable the thickness of the balloon envelope to be controlled accurately. Although balloons obtained by dipping generally give satisfaction, they nevertheless provide insufficient dimensional accuracy, which can lead to certain zones of the balloon being too thick, thereby increasing the cost of producing the balloon, or to certain other zones of the balloon not being thick enough, which can lead to the balloon being fragile."

On pages 25 and 26 of the present application, the Applicants detail the problems inherent in forming the balloon of Gau et al. The number of steps involved requires a staff to be particularly highly qualified in the manufacture of the balloon and considerably reduces the options for associating shapes and dimensions in a single part, which amounts to limiting the functions that it can perform. Gau et al recites that his balloon will have a final thickness of approximately 0.006 to 0.025 inches. Such a variation is considerably different from the balloon produced by the Applicants where the dimensional tolerance on the nominal thickness of the envelope lies in the range of 1% to 20%. Thus, it is unquestioned that the intragastric balloon of Gau et al can result in the shell having extremely wide variations in thickness throughout the structure. This fact is admitted by the Office in the rejection and balloons produced by this method provide insufficient dimensional accuracy which can lead to certain zones of the balloon being too thick, thereby increasing the cost of producing the balloon, or to certain other zones of the balloon not being thick enough, which can lead to the balloon being fragile. This is not acceptable considering the use to which the balloon is put.

So, it would have been non-obvious to one of ordinary skill in the art at the time the invention was made to utilize dimensional tolerance as claimed in view of *Gau et al.*, because the teachings of *Gau et al.* are to make the elastomeric shell by a method incapable of producing dimensional tolerance as claimed.

For the above reasons, Applicants submit that claims 25-28 are patentable over the cited prior art.

Claims 29-30 have been rejected under 35 U.S.C. 103 (a) as being unpatentable over *Gau et al.* (US 5,084,061) in view of *Thome et al.* (US 5,800,486).

To overcome this rejection, the Applicants submit an amended claim 29.

The amended claim 29 is now linked to claim 25 and all characteristics of claim 25 are comprised in the amended claim 29.

The amended claim 29 is new in view of *Gau et al.* due to the link with claim 25 concerning the dimensional tolerance of the elastomeric shell, and furthermore, as shown above, *Gau et al.* teaches a dipping method to make the elastomeric shell.

Thome et al. disclose forming a medical balloon by liquid injection molding from a flexible medical grade silicone (Col. 6, lines 49-51). But as *Gau et al.*, it never discloses the dimensional tolerance of the elastomeric shell as claimed. So, the one of ordinary skill in the art at the time the invention was made will not have the information concerning the effects of the liquid injection molding forming method and he will not have combined these two documents.

Furthermore, *Thome et al.* deals with small balloons used with catheter, these balloons having a big difference of size with intragastric balloons.

For the above reasons, Applicants submit that the amended claim 29 and the dependent claim 30 are patentable over the cited prior art.

CONCLUSION

With the amendments presented herein, it is believed that all the claims remaining in the application are in condition for allowance. Early and favorable action in this regarding is hereby respectfully requested. Should there be any minor informalities remaining, the Examiner is respectfully requested to call the undersigned attorney so that this case may be passed to issue at an early date.

Respectfully submitted,



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